REMARKS/ARGUMENTS

Claims 1-4 are pending in the application. Claim 1 has been amended to more clearly recite applicant's claimed composition. In particular, the claim amendment as amended now recites that "the at least one of active ingredients and principles are delivered, i.e., by the composition, to vaginal mucosa in a subject in need thereof" and that the claimed composition is "bioadhesive to said vaginal mucosa". The claim amendments are all entirely supported by the application as originally filed including, but not limited to, page 1, lines 1-3 and the Abstract. Therefore there is no issue of new matter raised by the claim amendments and the entry of these amendments into the file of the present application is respectfully requested.

Citation of Prior Art

In the copies of the forms attached at the end of the Office Action listing the prior art previously cited by the applicant, the Examiner has crossed out several references. The reason given by the Examiner for lining out (and not considering) the subject references is that no date has been provided for the references.

Attached to this response, therefore, is a substitute form re-listing the three references crossed off by the Examiner from the previous forms. Each citation is now provided with a date. Copies of the references are not, however, being re-supplied since they were already provided to the Examiner. The Examiner is respectfully requested to consider and make of record in the present application each of the references cited on the replacement form.

Claim Rejection Under 35 U.S.C. §112

At p. 3 of the Office Action the Examiner raises a new ground of rejection under 35 U.S.C. §112, second paragraph in that claim 1 is rejected as being allegedly indefinite. Applicant respectfully traverses the rejection.

The Office Action states, "It is unclear what the phrase of 'material used for converting the composition into a gel and to render it bioadhesive' would encompass. Applicant, however, submits that when one reads the entire phrase, and not just the truncated portion quoted by the Examiner, the meaning of the text is immediately apparent. That is, the applicant is not

generically claiming "any" material that would convert the composition into a gel and render it bioadhesive. Rather, applicant is claiming a specific material having this function. That is, the claim recites that hydroxyethylcellulose is the only material used for converting the composition into a gel and to render it bioadhesive. Anyone of ordinary skill in this field would well understand what a 'gel' is. As to the meaning of bioadhesive, the term "bioadhesion"is specifically defined by applicant at p. 1, lines 4-6 of the specification as filed.

The Examiner argues, in support of the rejection, that applicant provides no list of common gelling agents or what formula would constitute a "material used for converting the composition into a gel and render it bioadhesive". As indicated above, however, applicant does not need to provide such a list as he is presently claiming a specific species and not a genus. That is, applicant is under no obligation to disclose or otherwise teach one how to define the genus of all materials that could be used for converting the composition into a gel and to render it bioadhesive. Instead, applicant is instead reciting in claim 1 a specific material (a species) that fulfills the requirement, i.e., hydroxyethylcellulose. The fact that other materials may perform this function is moot insofar as applicant's responsibility under 35 U.S.C. 112, second paragraph is concerned. Applicant is not simply describing the claimed material by its function, i.e, in that it converts the composition into a gel and renders it bioadhesive. The material performing the indicated function is, moreover, specifically identified as hydroxyethylcellulose. Simply put, an applicant is under no obligation to define a genus when what is being claimed is, in fact, a species that is specifically identified, i.e., in this case as hydroxyethylcellulose.

The Office Action goes on to state, at the bottom of p. 3, that applicant provides no standard for ascertaining what a 'material used for converting the composition into a gel and to render it bioadhesive' would encompass. Based on this the Examiner states that one of ordinary skill in the art would not be reasonably apprised of the scope of the term, 'material used for converting the composition into a gel and to render it bioadhesive'. In response, applicant submits that a skilled artisan need only look to lines 4-5 wherein the claim recites, clearly and unambiguously, that hydroxyethylcellulose is the (only) material used for converting the composition into a gel and for rendering it bioadhesive. Since the meanings of 'gel' and

'bioadhesive' are, as indicated above, not in dispute and since 'hydroxyethylcellulose' is a known compound, applicant submits that there is no ambiguity at all present in the claim language.

Based on the arguments presented above applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejection Under 35 U.S.C. §102

At p. 4 of the Office Action the Examiner continues to maintain the rejection of claims 1, 3 and 4 under 35 U.S.C. §102 (b) over Arkin et al. (US 2003/0039704) for the reasons of record in the previous Office Action(s) filed on April 14, 2009 and December 16, 2009 and as discussed in the 'Response to Arguments' on pp. 4-5 of the Action. This ground of rejection is respectfully traversed.

The above rejection is discussed in detail in applicant's previous response filed in this application on March 16, 2010 and those remarks are expressly incorporated by reference into the present discussion. Further to those previous arguments, and in light of the matters raised by the Examiner in the 'Response to Arguments' in the present Office Action, applicant has amended claim 1 to move an important feature of the claimed composition from the preamble of the claim, where it was given no patentable weight by the Examiner, to the body of the subject claim. As now constituted, claim 1 reads as follows:

> "A composition in the form of an aqueous bioadhesive gel adapted for the delivery of at least one of active ingredients and principles to vaginal mucosa of a subject in need thereof, said composition comprising hydroxyethylcellulose as the only material used for converting the composition into a gel and to render it bioadhesive to said vaginal mucosa, glycerol and diethylene glycol monoethyl ether, together with at least one surfactant, preservative and acidifier."

Thus the features that the composition (1) delivers at least one of active ingredients and principles to a subject's vaginal mucosa; and that the composition is adapted so as to render it (2) bioadhesive to the vaginal mucosa are no longer recited 'merely' in the preamble of the subject claim wherein it can be treated as not constituting a claim limitation. Instead, the indicated

language is now found in the body of the claim wherein it must be considered as regards its impact on the patentability of the composition so claimed.

Thus, as previously argued in applicant's response dated March 16, 2010, the claimed composition is a composition that is specifically adapted for the delivery of at least one of active ingredients and principles to the vaginal mucosa of a subject in need thereof, wherein the composition is, in fact, bioadhesive to the vaginal mucosa, whereas Arkin et al., in contrast, is directed to pharmaceutical preparations adopted for topical administration for treating rosacea. As was previously noted in applicant's prior response, one having an ordinary level of skill in the relevant art would know, rosacea is a specific pathology affecting the skin, not the mucosa and particularly not the vaginal mucosa. The Arkin et al reference does not disclose a mucoadhesive formulation as recited in, e.g, claim 1, that is adapted for delivery to a subject's vaginal mucosa, or wherein the composition is bioadhesive to the vaginal mucosa.

As such, since the subject reference does not teach or otherwise disclose each and every feature of applicant's formulation as recited in claim 1, the subject claim is clearly not anticipated by the disclosure of Arkin et al. Moreover, as claims 3 and 4 are written in dependent form and each depend, directly or indirectly, upon claim 1, both of those claims additionally include all of the features recited in claim 1. Therefore, claims 3 and 4 are deemed not to be anticipated by Arkin et al for the same reasons as claim 1.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §102(b) of applicant's claims 1, 3 and 4 based on Arkin et al.

Claim Rejection Under 35 U.S.C. §103

Also at p. 4 of the Office Action the Examiner continues to maintain the rejection of claims 1-4 under 35 U.S.C. §103 over the Arkin et al. reference for the reasons provided in the prior Office Actions issued in this case and in the "Response to Arguments" on pp. 4-5 of the Action. This rejection is also respectfully traversed.

This ground of rejection, as well as that discussed above, was also discussed in applicant's previous response and those remarks are also incorporated by reference herein.

As mentioned above claim 1 is amended herein to further distinguish the composition recited thereby over the published Arkin et al. reference. Claim 1, in its amended form, thus is directed to a composition in the form of an aqueous bioadhesive gel adapted for delivery of at least one of active ingredients and principles. The materials are delivered to vaginal mucosa of one in need thereof. The composition comprises hydroxyethylcellulose as the only material used for converting the composition into a gel and for rendering it bioadhesive to the vaginal mucosa, plus glycerol and diethylene glycol monoethyl ether, together with at least one surfactant, preservative and acidifier.

In contrast, as noted above the composition disclosed by Arkin et al is for treating rosacea and, as such, it is topically applied upon the surface of the user's skin. It does not deliver an active ingredient and/or principle to the vaginal mucosa of a subject in need thereof, nor is it bioadhesive to the subject's vaginal mucosa. Furthermore, there is no suggestion anywhere within the Arkin et al reference that would suggest modifying the composition disclosed therein to one having an ordinary level of skill in this art such that it would meet the above-noted requirements recited in claim 1. That is, the treatment of rosacea does not call for delivering active ingredients and/or principles to the vaginal mucosa of a subject, i.e., due to the fact that rosacea is well-known to be a specific pathology affecting the skin. Furthermore, due to the fact that the Arkin et al composition is topically applied to the skin, the reference contains no teaching or suggestion to modify the composition(s) disclosed therein to render them, as recited in applicant's claim 1, bioadhesive to the vaginal mucosa.

The limitations discussed above, moreover, in claim 1 are set forth in the body of the subject claim, not in the preamble. As such they are entitled to due consideration of their distinguishing effect over the prior art and particularly over the Arkin et al. reference relied upon to reject applicant's claims.

Applicant thus respectfully submits that, for the reasons presented herein, claim 1 is clearly not obvious over Arkin et al. Moreover, remaining claims 2-4 each include all of the features recited in claim 1 from which they depend, and as such the subject dependent claims also are not obvious over Arkin et al for the same reason(s) as claim 1.

Summary

Taking into account the amendment(s) made to claim 1, together with the arguments presented above, applicant respectfully submits that claims 1-4 are all believed to be both novel and unobvious over the cited prior art reference of Arkin et al. The Examiner is, therefore, requested to reconsider and withdraw all of the present claim rejections and to issue a Notice of Allowance for all of applicant's claims.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON June 6, 2011.

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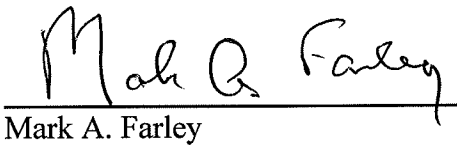
Respectfully submitted,



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